

AMENDMENTS TO THE CLAIMS:

Please amend the claims as follows:

1. (Currently Amended): A method for sterile filling a container with a substance, wherein the container includes a heat resealable stopper and a chamber for receiving the substance therein, the method comprising the steps of:

sealing the stopper to the container;

transporting the sealed, empty containers through an e-beam chamber;

directing an electron beam within the e-beam chamber onto a penetrable surface of the stopper to sterilize the penetrable surface;

introducing a needle within the e-beam chamber through the sterilized penetrable surface of the stopper;

introducing through the needle a substance into the chamber of the container;

withdrawing the needle from the stopper upon introducing the substance through the needle and into the chamber;

~~transporting the filled containers out of the e-beam chamber; and~~

applying energy to the penetrated surface of the stopper and hermetically sealing same.

2. (Original): A method as defined in claim 1, further comprising the step of subjecting the sealed, empty container to radiation capable of penetrating through the stopper and chamber and sterilizing the container prior to transporting the container through the e-beam chamber.

3. (Original): A method as defined in claim 2, wherein the step of subjecting the sealed container to radiation capable of penetrating through the stopper and chamber includes subjecting the container to gamma radiation.

4. (Original): A method as defined in claim 1, further including the step of impinging e-beam radiation onto the needle within the e-beam chamber to maintain the needle sterile during filling of a plurality of containers.

5. (Original): A method as defined in claim 1, wherein the step of applying energy to the penetrated surface of the stopper includes transmitting radiation onto the penetrated surface of the stopper to hermetically seal any needle aperture formed within the stopper.

6. (Original): A method as defined in claim 1, wherein the substance is a medicament.

7. (Original): A method as defined in claim 1, wherein at least one of the current, scan width, position and energy of the electron beam is selected to achieve at least about a 3 log reduction in bio-burden on the penetrable surface of the stopper.

8. (Original): A method as defined in claim 7, wherein at least one of the current, scan width, position and energy of the electron beam is selected to achieve at least about a 6 log reduction in bio-burden on the penetrable surface of the stopper.

9. (Original): A method as defined in claim 1, further comprising the step of introducing a preservative-free medicament through the needle and into the chamber of the container.

10. (Original): A method as defined in claim 1, further comprising the step of providing a stopper having a needle penetration region that defines a predetermined color and opacity that substantially absorbs laser radiation at a predetermined wavelength and substantially prevents the passage of said laser radiation through a predetermined wall thickness thereof.

11. (Original): A method as defined in claim 1, further comprising the step of providing a stopper having a needle penetration region defining a predetermined color and

opacity that causes laser radiation at a predetermined wavelength and power to hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period.

12. (Original): A method as defined in claim 1, further comprising the step of providing a conveyor within the e-beam chamber and transporting the container on the conveyor through the e-beam chamber, and providing at least one reflective surface adjacent to the conveyor for reflecting electron beam radiation onto at least one side of the container.

13. (Original): A method as defined in claim 1, further comprising the step of providing a plurality of e-beam sources and directing an electron beam from each e-beam source into a respective region of the e-beam chamber.

14. (Original): A method as defined in claim 13, further comprising the step of focusing each of a plurality of e-beam sources onto a respective surface area of the container.

15. (Original): A method as defined in claim 1, further comprising the step of transporting the container through the e-beam chamber along a path defining a first leg and a second leg, focusing the electron beam onto the penetrable surface of the stopper within the first leg of the path, and introducing the needle through the sterilized penetrable surface of the stopper within the second leg of the path.

16. (Original): A method as defined in claim 15, wherein the path is approximately u-shaped, the first leg is a one leg of the u-shaped path, and the second leg is another leg of the u-shaped path.

17. (Original): A method as defined in claim 1, further comprising the step of drivingly mounting a plurality of needles within the e-beam chamber, driving the plurality of needles into engagement with a plurality of resealable stoppers and piercing the stoppers, and introducing the substance through the needles and into the chambers of the containers.

18. (Original): A method as defined in claim 1, further comprising the step of ionizing air within the e-beam chamber for sterilizing a surface of the needle.

19. (Original): An apparatus for sterile filling a container with a substance, wherein the container includes a heat resealable stopper and a chamber for receiving the substance therein, the apparatus comprising:

an e-beam chamber for receiving the container therein;

an e-beam source for directing an electron beam within the e-beam chamber onto a penetrable surface of the stopper to sterilize the penetrable surface;

a needle movably mounted within the e-beam chamber, wherein the needle is movable into and out of engagement with the resealable stopper for piercing the resealable stopper and introducing a substance through the stopper and into the sealed chamber of the container; and

an energy source connectable in thermal communication with the penetrable surface of the resealable stopper for applying energy to the penetrable surface after withdrawing the needle therefrom to hermetically seal same.

20. (Original): An apparatus as defined in claim 19, further comprising a first radiation source located external to the e-beam chamber for generating radiation capable of penetrating through the stopper and chamber of the container and sterilizing the container prior to transporting the container through the e-beam chamber.

21. (Original): An apparatus as defined in claim 20, wherein the radiation source is a gamma radiation source.

22. (Original): An apparatus as defined in claim 19, wherein the e-beam source and the needle located within the e-beam chamber are positioned relative to each other to cause e-

beam radiation from the e-beam source to impinge on the needle and maintain needle sterility during filling of a plurality of containers.

23. (Currently Amended): An apparatus as defined in claim 19, ~~further comprising wherein the energy source is a second radiation source located outside of the e-beam chamber~~ and configured to transmit radiation at a predetermined wavelength and power onto the stopper to hermetically seal a region of the stopper penetrated by the needle.

24. (Currently Amended): An apparatus as defined in claim 23, wherein the ~~second~~ radiation source is a laser that transmits laser radiation at a predetermined wavelength.

25. (Original): An apparatus as defined in claim 23, further comprising a container including a heat resealable stopper and a chamber for receiving the substance therein, wherein the stopper includes a needle penetration region that defines a predetermined color and opacity that substantially absorbs laser radiation at said predetermined wavelength and substantially prevents the passage of said laser radiation through a predetermined wall thickness thereof.

26. (Original): An apparatus as defined in claim 25, wherein the needle penetration region of the stopper defines a predetermined color and opacity that causes laser radiation at the predetermined wavelength and power to hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period.

27. (Original): An apparatus defined in claim 19, further comprising a conveyor extending within the e-beam chamber, a motor drivingly coupled to the conveyor for moving the conveyor and, in turn, transporting the container on the conveyor through the e-beam chamber, and a control unit coupled to the e-beam source and the motor, wherein the control unit controls at least one of the current, scan width, and energy of the e-beam source and the speed of the

conveyor to achieve at least about a 3 log reduction in bio-burden on the penetrable surface of the stopper.

28. (Currently Amended): An apparatus defined in claim 24 27, wherein the control unit controls at least one of the current, scan width, and energy of the e-beam source and the speed of the conveyor to achieve at least about a 6 log reduction in bio-burden on the penetrable surface of the stopper.

29. (Original): An apparatus as defined in claim 19, further comprising a conveyor extending within the e-beam chamber for transporting a container on the conveyor through the e-beam chamber, and at least one reflective surface located adjacent to the conveyor for reflecting electron beam radiation onto at least one side of the container.

30. (Original): An apparatus as defined in claim 19, further comprising a plurality of e-beam sources, each directing an electron beam into a respective region of the e-beam chamber.

31. (Original): An apparatus as defined in claim 30, wherein each e-beam source focuses its electron beam onto a respective surface area of the container.

32. (Original): An apparatus as defined in claim 19, further comprising a container path extending within the e-beam chamber for transporting the container along the path and through the e-beam chamber, wherein the path defines a first leg and a second leg, the electron beam is focused onto the penetrable surface of the stopper within the first leg of the path, and the needle is movably mounted on the second leg of the path for penetrating the sterilized penetrable surface of the stopper within the second leg of the path.

33. (Original): An apparatus as defined in claim 32, wherein the path is approximately u-shaped, the first leg is a one leg of the u-shaped path, and the second leg is another leg of the u-shaped path.

34. (Original): An apparatus as defined in claim 19, further comprising a plurality of needles drivably mounted within the e-beam chamber, wherein each needle is drivable into and out of engagement with a resealable stopper of a respective container.

35. (Currently Amended): An apparatus as defined in claim 19, further comprising an energy source in the form of a laser source for transmitting laser radiation at a predetermined wavelength and power, and a container including a heat resealable stopper and a chamber for receiving the substance therein, wherein the resealable stopper includes a thermoplastic body defining (i) a predetermined wall thickness in an axial direction thereof, (ii) a predetermined color and opacity that substantially absorbs the laser radiation at the predetermined wavelength and substantially prevents the passage of the radiation through the predetermined wall thickness thereof, and (iii) a predetermined color and opacity that causes the laser radiation at the predetermined wavelength and power to hermetically seal a needle aperture formed in the needle penetration region thereof in a predetermined time period.

36. (Original): An apparatus as defined in claim 35, wherein the predetermined time period is less than or equal to approximately 2 seconds.

37. (Original): An apparatus as defined in claim 35, wherein the predetermined color of the material is gray, and the predetermined opacity is defined by a dark gray colorant added to the stopper material in an amount within the range of about 0.3% to about 0.6% by weight.

38. (Original): An apparatus for sterile filling a container with a substance, wherein the container includes a heat resealable stopper and a chamber for receiving the substance therein, the apparatus comprising:

an e-beam chamber for receiving the container therein;

first means for directing an e-beam beam within the e-beam chamber onto a penetrable surface of the stopper to sterilize the penetrable surface;

second means located within the e-beam chamber and movable into and out of engagement with the resealable stopper for piercing the resealable stopper and introducing a substance through the stopper and into the sealed chamber of the container; and

third means for applying energy to the penetrable surface of the resealable stopper after withdrawing the second means therefrom to hermetically reseal the penetrable surface.

39. (Original): An apparatus as defined in claim 38, wherein the first means is an e-beam source.

40. (Original): An apparatus as defined in claim 38, wherein the second means is a needle.

41. (Original): An apparatus as defined in claim 38, wherein the third means is a laser.

42. (Original): An apparatus as defined in claim 38, further comprising fourth means for subjecting the sealed, empty container to radiation capable of penetrating through the stopper and chamber and sterilizing the container prior to transporting the container through the e-beam chamber.

43. (Original): An apparatus as defined in claim 38, wherein the first means and the second means are configured relative to each other to achieve at least about a 3 log reduction in bio-burden on an external surface of the second means.

Please add the following new claims:

44. (New): An apparatus as defined in claim 38, wherein the third means applies energy to the penetrable surface of the stopper to reseal the surface outside the e-beam chamber.

45. (New): A method as defined in claim 1, further comprising the step of transporting the filled containers out of the e-beam chamber prior to applying energy to the penetrated surface of the stopper and hermetically sealing same.

46. (New): An apparatus as defined in claim 19, wherein the energy source is configured to apply energy to the penetrated surface and hermetically seal same outside the e-beam chamber.